

### **DETAILED ACTION**

This action is in response to the applicant's amendment received 05 October 2009. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below. Claims 9 and 32-34 remain canceled. Claims 13 and 15-21 remain withdrawn from consideration.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-8, 10-12, 14, and 22-31 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1, 10-12, 14, 22-26, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morton (U.S. Patent No. 1,558,037 - cited 10/29/08) and Smith et al. (U.S. Patent No. 4,799,484).** It is noted that sufficient structure has been

recited for increasing the bond between the adhesive and the hole (for example, see claim 22). Therefore, 112, sixth paragraph, has not been invoked.

Morton discloses an armed suture (see entire document) comprising a needle (1) having first and second opposed ends and a blind hole (2) formed in the first end and extending longitudinally, the hole including an upper edge, a sidewall, a bottom wall, and a length therebetween (see Figure 3) having a first diameter greater than the diameter of a multi-braided or monofilament suture (4; so that the suture may be inserted), and a second diameter proximate the bottom wall that is greater than the first diameter proximate the upper edge, thus forming a bottle shape, wherein the hole may also accommodate sutures smaller than the suture shown, thus may accommodate a range of differently-sized sutures therein. Morton further discloses the inside of the hole is scarified (or roughened bond increasing means or unpolished; see claims 1 and 22) in such a manner as to provide adequate anchorage of the suture therein (for example, see page 2, lines 60-63) and an adhesive permits the suture to be inserted into the hole and forms an annular mass that substantially surrounds the end of the suture along the length of the hole forming a bottle-shaped interlock (for example, see page 1, lines 32-35). Morton fails to disclose the blind hole has a conical tip at the bottom wall including an apex such that a space is formed between the end of the suture and the bottom wall of the blind hole.

Smith discloses a needle having blind hole, wherein the suture may be attached to the needle with an adhesive (see entire document). Smith teaches the blind hole (18) has a conical tip at the bottom wall including an apex (for example, see Figures 1a-1c)

such that a space is formed between the end of the suture and the bottom wall of the needle when inserted (not illustrated; see Martinez's patent 4,127,133 Figure 1 for illustration of suture inserted within same shaped blind hole). Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Smith to the blind hole of Morton would have yielded predictable results and resulted in an improved system, namely, a system that provides a blind hole that enables a larger amount of adhesive to be contained proximate the bottom wall having a conical tip (i.e., in the space between the end of the suture and the bottom wall of the blind hole), thus enhancing the security of the suture therein.

Claims 11 and 23-25 are being treated as product by process limitations, in that "said suture hole is formed by laser drilling," "said roughened portion is reamed," "said roughened portion is laser drilled," and "said roughened portion is etched," refers to the process of forming the suture hole and its surface and not to the final product created. As set forth in MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985). Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, an armed suture as described above wherein the suture hole is formed by laser drilling, and the roughened surface is reamed, laser

drilled, or etched, is directed to the method of making the armed suture hole and its roughened surface and not to the final product made. It appears that the product disclosed by Morton as modified by Smith would be the same as that claimed; especially since both applicant's product and the prior art product have the same final structure of an armed suture comprising a blind hole having a roughened surface.

**Claims 2-8 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morton and Smith as applied to claim 1 above, and further in view of Korthoff et al. (U.S. Patent No. 5,156,615 - cited 10/29/08).** Morton as modified by Smith discloses the claimed invention except for an adhesive that is curable as claimed or that the adhesive is specifically cyanoacrylate.

Korthoff discloses bonding a suture attached to a needle using adhesives (see entire document). With respect to claims 2-8, Korthoff teaches that cyanoacrylate (which is curable by exposure to electromagnetic radiation, such as UV light, and further curable by a second curative agent, such as water or heat) is a preferred adhesive for bonding the suture within a hole in the needle, since cyanoacrylate possesses excellent adhesive characteristics (for example, see column 9, lines 18-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use cyanoacrylate as the adhesive, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. Utilizing cyanoacrylate would ensure an excellent bond, thus further reducing the risk of the suture detaching from the needle during use.

With further respect to claims 27-29, the applicant admits that a low viscosity, UV-curable, cyanoacrylate adhesive having a cyanoacrylate secondary cure mechanism is well known and is available under the name LOCTITE Product 4302. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use LOCTITE Product 4302 as the adhesive, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELANIE TYSON** whose telephone number is

(571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./  
Examiner, Art Unit 3773  
January 8, 2010

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